REMARKS OF
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TO
GENERIC DRUG CONFERENCE
OF L. F. ROTHSCHILD AND COMPANY
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This is my first trip to New York City since the country and the world were shaken by the recent upheaval in our stock markets. As you might imagine, it is a constant topic of discussion by Members of Congress.

You have heard it said in the press many times. Congress got the message that the financial markets are worried about our future.

Actually, Congress has understood for a long time that our budget deficit would lead to serious economic troubles. Congress has talked a lot about reducing the deficit, and we have passed seven budget reconciliation bills. We have been unable, though, to reach consensus on long-term deficit reduction. To many people this deadlock appears to be partisan bickering.

As Chairman of the Subcommittee on Health and the Environment, I see it in different terms -- in human terms. I see deficit reduction as an excuse for some to ignore many pressing, unmet health needs.

- 37 million Americans have no form of health insurance. This is significantly worse than when Ronald Reagan took office.

- o High infant mortality rates persist in spite of dramatic advances in medical care. The U.S. rate is last among 20 industrialized nations. A black infant born in Indianapolis has less chance of living to one year of age than an infant born in Trinidad.

- o Elderly men and women with spouses in nursing homes are forced into poverty before Medicaid will help. The current rules allow the at-home spouse to keep a mere $340 per month, a car worth less than $3500, and liquid assets of $1800.

We must reduce our deficit, but I will never ignore the unmet health care needs of our citizens to do it.

As we speak, the budget summit is playing out this tension between human health and our nation's perceived financial health from lower deficits.

Budget Summit and Health

It is unclear how the budget summit will find the $23 billion of deficit reductions that are required. It is also unclear whether existing health programs will be sacrificed.

The House budget bill would cut almost $9 billion from the Medicare program over the next three years. Those savings come primarily from reduced payments to health care providers.

I worry about these deep cuts. Hospitals and doctors cannot continue to provide high quality care regardless of our payment levels. Members of Congress claim these cuts will not affect Medicare beneficiaries. Maybe not in 1988. But there is a point where we will either jeopardize quality, or push providers out of the Medicare program.

The news is not all bad. The House budget bill contains additional funds for AIDS research at NIH and drug review at FDA. It also provides new money for expanded Medicaid coverage for children and pregnant women.

There appears to be broad, bipartisan support for new spending in selected areas. However, I fear this support could be eroded in the hypersensitive climate of a post-Black Monday budget summit.

There is another possibility that is even worse. A stalemated budget summit followed by Gramm-Rudman cuts.

Gramm-Rudman is mindless. Its beauty, say the admirers, is that it does not distinguish between programs. I call it madness to cut equally from AIDS funding as the epidemic spreads or from FDA's budget when we need faster approvals.

It is too early to know whether the budget summit will succeed, and if it does, whether the health cuts will be deeper. All one can

say now is that the current attitude in Washington is to make significant progress on the deficit, partly through tax increases.

Medicare Catastrophic Drug Coverage

This conference is about generic drugs. I know one of your primary concerns is how the next budget cuts will affect the new Medicare Catastrophic drug benefit.

The short answer is -- they won't.

The Medicare Catastrophic bill represents the first major improvement in benefits since 1965. It is an extremely important provision because drugs are the second largest out-of-pocket expense for the elderly. The Congressional Budget Office estimates that over 5 million Medicare beneficiaries currently spend over $500 a year in prescription drugs. The average annual cost of drugs for these 5 million elderly is $1000.

The cost of adding this new drug coverage is significant -- $6.4 billion over four years -- but it does not require federal spending. The benefit is funded totally by higher premiums on Medicare beneficiaries. Not a single dollar of general revenues will be used.

Aside from any budget concern, this bill has major importance to the drug industry -- both brand and generic.

The House bill would cover, starting in 1989, all outpatient prescription drugs after a $500 deductible is met. Medicare would then pay for 80% of the cost of drugs. When generic substitutes are available, Medicare would pay at the generic rate unless the prescribing doctor handwrites on the prescription that the brand drug is medically necessary.

With Medicare paying for drugs for low-income Medicare beneficiaries who are also eligible for Medicaid, state Medicaid programs will save money. The House bill requires the states to use that money for Medicare beneficiaries with income below the poverty level. States would pay their Medicare premiums and cover their Medicare deductible.

The Senate bill phases in coverage very slowly. Only in 1993 would all drugs be covered.

Starting in 1990, the Senate bill would pay for chemotherapy and immunosuppressive drugs. In 1991 and 1992, cardiovascular and diuretic drugs would be included. For all these, a $600 deductible would be required before Medicare would pay its 80% share. Generics would be required as in the House bill. The state Medicaid savings would not be recaptured as in the House bill.

The Senate bill succeeds only in its lack of aggressiveness. By 1992, the Senate would cover 2.4 million beneficiaries while the House would reach 6.2 million.

The brand name drug companies conducted a multi-million dollar national attack on the bill. They claimed in their extensive advertisements that they were only concerned about the high premiums for the elderly. If that were so, they could lower their unprecedented prices.

The real reason for their opposition is their fear of Congressional cost controls.

The House and Senate bills represent the first time that the Federal government will pay for drugs with a national set of rules. As you know, there are 50 different payment rules in the Medicaid program. The bills also represent the first time that Medicare will collect data on the prices charged for prescription drugs.

If Congress sees manufacturer price increases of the magnitude of the last five years, brand name companies assume Congress will enact cost controls to keep Medicare premiums down. They are right.

For generic drugs, the Medicare Catastrophic drug benefit is yet another seal of government approval. But Medicare will be pro-generic for one simple reason -- price. Higher prices mean higher premiums. Generic substitution is the most important means of holding costs down.

The brand name companies attacked the use of generics in the two bills with their usual litany of horror stories. FDA has rejected

their unsubstantiated slurs against generics. So has the Congress.

The Administration now supports the Senate drug benefit. It is certain that a drug benefit, with a generic preference, will be enacted. With Medicare's preference for generics, other health insurers and providers will be encouraged to make greater use of generics.

Exclusivity and 1984 Waxman-Hatch Law

Legislative activity always attracts the most attention. Often, the mundane world of implementing complex laws -- like the 1984 Drug Price Competition and Patent Term Restoration Act -- go unnoticed.

It has been three years since the so-called Waxman-Hatch amendments were signed. Overall, I am extremely pleased with the work of the FDA and with the impact of the law.

As you know, the 1984 law contained a number of "exclusivity provisions". Under these new rules, companies are rewarded with FDA-enforced marketing rights for new drugs and new uses of previously approved drugs. For a new drug with no patent, or weak patent protection, a five year exclusivity from generics means everything. For a new use, three years of exclusivity can be most valuable.

As a political compromise, the law also included exclusivity from generics for drugs approved in the two years prior to the 1984

enactment.

As one might expect, inventive lawyers and company executives have tried to fit their companies into the criteria for these economic rules. FDA's responses to these efforts have, so far, followed the language and spirit of the law.

What is troubling, and new, are the efforts by some companies to create new exclusivity rules for themselves. Warner-Lambert claims that its drug, Lopid, deserves greater protection because of breakthrough research. Mylan says its drug, Maxide, deserves the same.

If Congress accedes to these two requests, many more will follow.

I have opposed these two companies and will oppose all other single company requests. The compromise was made in 1984. The exclusivity rules are set. The competing public interests of lower priced generics and new, breakthrough drugs are balanced. Further extensions of the exclusivity rules are special interest requests that should be defeated.

Orphan Drug Amendments

With all the attention on FDA guaranteed marketing rights, the Orphan Drug Act might be a casualty.

The Orphan Drug Act contains a number of incentives for the

development of drugs for rare diseases -- or orphan drugs. Unquestionably, the most important is the seven year exclusivity rule. Unlike the exlusivity provisions in the Waxman-Hatch Amendments, the Orphan Drug Act provides an absolute monopoly. FDA is prohibited from approving any other company for the same drug for the same rare disease, even if the second company is willing to do its own New Drug Application, complete with clinical trials.

This total ban on competition was intended to comfort potential sponsors. If they would undertake the development of drugs with little commercial value, Congress would guarantee them all the potential sales.

Offering these incentives in an atmosphere of heightened Congressional and public expectations has succeeded. Four and one-half years after enactment, development on 159 drugs for rare diseases has begun and 19 of those are approved.

But success draws attention. It is now clear that some companies are misusing the exclusivity provision in the Orphan Drug Act. Instead of an incentive to develop drugs of little commercial value, the Act has become a shield for highly profitable drugs.

This issue came to a head with the recent approval of Eli Lilly's human growth hormone. Even though the patent population of 10,000 children is quite small, the annual price of more than $10,000 per child gives it significant commercial value.

With exclusivity in hand, Lilly can now block four other companies from competing, and presumably, reducing the price.

Congress was trying to entice companies, one at a time, to make unprofitable and marginally profitable orphan drugs. We did not anticipate prices like those for AZT and human growth hormone. They have set a troubling precedent. Even drugs for rare diseases can now be a smashing financial success.

To address this matter, the Energy and Commerce Committee recently passed my orphan drug legislation, H.R. 3459. It would restrict the exclusivity rule to an extent. FDA could approve a second company that is willing to file its own new drug application, with all necessary clinical studies conducted by the company. Generic applications and paper new drug applications, in which the company does not conduct the necessary studies, would continue to be blocked by the exclusivity rule.

A drug that is only marginally profitable would be unaffected. No second company would spend millions of dollars to share a small market. But drugs, like human growth hormone, with sizable markets will have competition.

The goal of the bill is simply stated. If orphan drugs have commercial value, the company developing the drug does not need the additional incentive of exclusivity.

I expect the Orphan Drug bill to be considered in the House of Representatives this year.

Drug Prices

The very high prices for drugs like AZT and human growth hormone are a symptom of a larger problem. It appears that brand name companies have decided that there are no limits to what they can charge.

They claim their price increases are justified by ever-increasing costs of research and development. At the July, 1985, hearing of my Subcommittee on Health and the Environment on drug price increases, the drug companies vigorously made just such an argument.

I took them at their word and asked for proof. In preparation for the second Subcommittee hearing on price increases, in April of this year, I conducted a survey of the 25 largest research-based companies. Their combined drug sales represented 2/3 of all sales.

Their data indicated that their prices had risen 3 times faster than necessary. For those companies, for the years 1982-1986, revenues from price increases were $4.7 billion. Revenues from volume increases and new drugs were another $4.2 billion. During the same time period, the total increase in R and D costs was $1.6 billion.

Even when faced with the facts, the Pharmaceutical Manufacturers Association persists with the unfounded claims and the companies with their price increases.

High prices make drugs inaccessible. They were a major factor in Congress deciding to cover drugs under Medicare. Continued price hikes will prompt further Congressional responses.

Conclusion

The 100th Congress has considered relatively few bills affecting the drug industry. If we are short on quantity, though, we have compensated with importance.

The Medicare Catastrophic bills will have far-reaching effects on the brand and generic industries. The Orphan Drug Act tests our commitment to marshalling our drug development resources for the disadvantaged. I believe the Congress is hitting the bull's eye with both bills.